MAY 2 6 2011

APPENDIX 1

510(K) SUMMARY OR 510(K) STATEMENT

Endologix AFX Introducer System
510(k) Summary – K110090
May 6, 2011

1. **Company:** Endologix Incorporated
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2. **Proprietary Trade Name:** Endologix AFX Introducer System

3. **Classification Name:** Catheter, Introducer (21 CFR 870.1340)

4. **Product Code:** DYB

5. **Product Description:**

The Endologix AFX Introducer System consists of an Introducer Sheath (45 cm working length) and two Dilators. The system is enclosed in a sterile package. During clinical use, the system will allow introduction of a standard 0.035" guidewire within its inner lumen.

- *Introducer Sheath:* The Introducer Sheath provides a conduit for introducing other interventional devices, including guidewires and interventional catheters, into the vasculature. The main components of this assembly are a hydrophilically-coated, PTFE lined, 55D Pebax introducer sheath, acrylobutylstyrene (ABS) hemostasis valve housing with butyl rubber valve, and silicone gasket assembly, 3 way stopcock/valve, and sideport diethylhexyl phthalate (DEHP)-free polyvinylchloride (PVC) tubing. The Pebax introducer sheath also includes an embedded stainless steel braid for increased strength and kink resistance, and embedded Vectran® strands for increased longitudinal strength. The distal tip of the introducer sheath includes an embedded radiopaque marker composed of 90% Platinum/10% Iridium.

- *Dilators:* The dilators for the system are used to provide support and stability to the Introducer Sheath during deployment into the vasculature. The dilators are designed specifically for the Endologix AFX Introducer System and can accommodate a 0.035" guidewire through the central lumen. Two dilators are included with the AFX Introducer System. Both dilators are included within the package. One dilator is a single lumen device and one dilator is a dual lumen device. Both dilators are composed of 63D Pebax with 20% Barium Sulfate ($BaSO_4$) for radiopacity and include a

hydrophilic coating on the outer surface. These dilators are designed in diameter and length to be placed within the AFX Introducer Sheath component. The dilators have a tapered, atraumatic distal tip. The proximal end of the dilators includes a luer port. The dilators provide stiffness to the assembly so that the introducer sheath can be placed within the vasculature during a standard vascular access.

6. Indications:

The AFX Introducer System facilitates the introduction of guidewires, catheters, and other medical devices into the vasculature and minimizes blood loss associated with such introduction.

7. Substantial Equivalence:

Documentation provided includes mechanical test results and detailed comparison to the predicate devices demonstrate that the Endologix AFX Introducer System is substantially equivalent to the Gore Introducer Sheath with Silicone Pinch Valve (K082356 and K032073), the Cook Medical Extra Large Check-Flo Introducers (K902469), and the Endologix IntuiTrak Introducer Sheath (P040002/S021). Reference is also made to the following Endologix products to support the clearance of the Endologix Dual Lumen Dilator: Dual Lumen Catheter (K991601) and IntuiTrak Single Lumen Dilator (P040002/S021)

Testing includes sterilization validation, shelf-life packaging validation, biocompatibility testing, and performance testing to ISO 10555-1 for intravascular catheters. A summary of this testing is provided in the following tables.

Table 7-1: Steriliztation Validation

Test	Test Description	Result (Pass/Fail)
Sterility	Validation of the ethylene oxide sterilization cycle in accordance with ISO 11135-1 to verify that the ethylene oxide sterilization process provides a SAL of 10^{-6}	Pass

Table 7-2: Shelf-Life Packaging Validation

Test*	Test Description	Result (Pass/Fail)
Visual Inspection	Visual inspection of the packaging (inner and outer pouch) to identify any anomalies that could impact integrity of the package	Pass
Bubble Emission	ASTM F2096-04 Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization	Pass
Dye Penetration	ASTM F1929-98 (2004) Standard Test Method for Detecting Seal Leaks in Porous medical Packaging by Dye Penetration	Pass
Peel Test	ASTM F88M-09 Standard test method for seal strength of flexible barrier materials	Pass

* Testing per ISO 11607-1: Packaging for Terminally Sterilized Medical Devices

Table 7-3: Biocompatibility

Test	Test Description	Result (Pass/Fail)
Cytotoxicity ISO 10993-5	MEM Elution Using L0929 Mouse Fibroblast Cells	Pass
Sensitization ISO 10993-10	Murine Local Lymph Node Assay	Pass
Intracutaneous Reactivity ISO 10993-10	Intracutaneous Irritation Test	Pass
Acute Systemic Toxicity ISO 10993-11	Acute Systemic Injection Test	Pass
Hemocompatibility ISO 10993-4	Complement Activation Hemolysis Assay Partial Thromboplastin Time Platelet and Leukocyte Counts	Pass Pass Pass Pass
Pyrogenicity USP < 151>	Rabbit Pyrogen Test	Pass

Table 7-4: Performance Testing

Test*	Test Description	Result (Pass/Fail)
Leak Testing	Connection fittings and valve seal do not leak liquid when tested at 3.0 PSI	Pass
Bond and Component Tensile Strength	Break force of each bond meets or exceeds requirements	Pass
Particle Size: 10-25µm <6,000 >25µm <600	USP <788> requirements for particulate matter in injection solutions of 100 mL or less in volume	 Pass Pass

* Testing per ISO 10555-1 for intravascular catheters

Table 7-5: Compatibility with Other Devices

Test*	Test Description	Result (Pass/Fail)
Guidewire Passage	Verify the delivery system accepts 0.035" guidewire	Pass
Crossing Profile	Verify the catheter dimensions comply with product specifications	Pass
Open Lumen Testing	Ensure that the guidewire passes through the system while in a bent position	Pass
Kink Test	Ensure that the delivery system will not kink when inserted through and retracted from the introducer sheath at a 90° angle	Pass
Introducer Sheath Transfer Force Testing	Verify transfer force is in compliance with product specifications	Pass

* Testing per ISO 25539-1: Cardiovascular Implacts – Endovascular Devices

Table 7-6: Endologix AFX Introducer System Predicates Comparison Table

Feature	**Gore Introducer Sheath with Silicone Pinch Valve (K082356 and K032073)**	**Cook Medical Extra Large Check-Flo Introducers (K902469)**	**Endologix Dual Lumen Catheter (K991601)**	**Endologix IntuiTrak Delivery System** - Introducer Sheath - - Single Lumen Dilator - **(P040002 / S021)**	**Endologix AFX Introducer System (K110090)**
Product Code	DYB	DYB	DQY	---	DYB
Intended Use/ Indications for Use	Intended for use to facilitate the introduction of guidewires, catheters and other interventional medical devices into the vascular system, and to minimize blood loss associated with such introduction	Intended for use to facilitate the introduction of guidewires, catheters and other interventional medical devices into the vascular system, and to minimize blood loss associated with such introduction	For use in a two guidewire procedure	Integrated into the IntuiTrak Delivery System; intended for use to facilitate the introduction of guidewires, catheters and other interventional medical devices into the vascular system, and to minimize blood loss associated with such introduction	Introducer Sheath with Single Lumen Dilator Intended for use to facilitate the introduction of catheters and other medical devices into the vasculature and to minimize blood loss associated with such introduction Introducer Sheath with Dual Lumen Dilator Intended for use in a two guidewire procedure to facilitate the introduction of catheters and other medical devices into the vasculature and to minimize blood loss associated with such introduction

Feature	Gore Introducer Sheath with Silicone Pinch Valve (K082356 and K032073)	Cook Medical Extra Large Check-Flo Introducers (K902469)	Endologix Dual Lumen Catheter (K991601)	'Endologix IntuiTrak Delivery System - Introducer Sheath - - Single Lumen Dilator - (P040002 / S021)	Endologix AFX Introducer System (K110090)
Material	Materials biocompatible for use in the vasculature	Materials biocompatible for use in the vasculature	Materials biocompatible for use in the vasculature including: • Pebax (7233) components • Polycarbonate luer • PTFE Braided lumen	Materials biocompatible for use in the vasculature including: • Pebax for the sheath (72D) and dilator (63D) components • PTFE liner on the inner diameter of the sheath • Hydrophilic coating on the Introducer sheath and dilator • ABS handle • Silicone gasket • Butyl Rubber Trocar Valve [K945719] • DEHP free PVC Side port tubing • Polycarbonate/silicone stopcock	Materials biocompatible for use in the vasculature including: • Pebax for the sheath (72D) and dilator (63D) components • PTFE liner on the inner diameter of the sheath • Hydrophilic coating on the Introducer sheath and dilator • ABS handle • Silicone gasket • Butyl Rubber Trocar Valve [K945719] • DEHP free PVC Side port tubing • Polycarbonate and polyether stopcock
Radiopaque Marker	Radiopaque dilator for fluoroscopic visibility	unknown	• Gold	• 90% Platinum/10% Iridium marker band embedded on the distal tip of the Introducer Sheath • Dilators are loaded with 30% $BaSO_4$	• 90% Platinum/10% Iridium marker band embedded on the distal tip of the Introducer Sheath • Dilators are loaded with 20% $BaSO_4$
Dimensions	Four configurations provided: • 18 Fr – 22Fr • 70 cm usable dilator length • 30 cm sheath length • Central dilator lumen compatible with 0.035" guidewire	Five configurations provided: • 20 Fr – 24 Fr • 56 -81 cm usable dilator length • 25 – 65 cm outer sheath length • Central lumen compatible with 0.035" guidewire	A single catheter configuration provided: 9 Fr Catheter • 90 cm usable length • Central dilator lumen compatible with 0.035" guidewire	A single dilator configuration provided: 19 Fr Dilator • 80.6 cm usable dilator length • Central dilator lumen	A single dilatory configuration is provided: 17 Fr Dilator • 69 cm usable dilator length • 3.1 cm tapered dilator tip • 17 Fr dilator outer diameter • 6.4 mm (19 Fr) outer sheath diameter • 45 cm sheath length • 2 dilators included (single and dual lumen) • Central guidewire lumen (dilators)

Feature	Gore Introducer Sheath with Silicone Pinch Valve (K082356 and K032073)	Cook Medical Extra Large Check-Flo Introducers (K902469)	Endologix Dual Lumen Catheter (K991601)	Endologix IntuiTrak Delivery System - Introducer Sheath - - Single Lumen Dilator - (P040002 / S021)	Endologix AFX Introducer System (K110090)
Biocompatibility	Materials biocompatible for use in the vasculature	Materials biocompatible for use in the vasculature	Materials biocompatible for use in the vasculature	Materials biocompatible for use in the vasculature	Materials biocompatible for use in the vasculature
Sterilization	Provided sterilized to a sterility assurance level (SAL) of 10^{-6} by ethylene oxide sterilization process	Provided sterilized to a sterility assurance level (SAL) of 10^{-6} by ethylene oxide sterilization process	Provided sterilized to a sterility assurance level (SAL) of 10^{-6} by ethylene oxide sterilization process	Provided sterilized to a sterility assurance level (SAL) of 10^{-6} by ethylene oxide sterilization process	Provided sterilized to a sterility assurance level (SAL) of 10^{-6} by ethylene oxide sterilization process
Introducer Sheath Simulated Use Testing	Compliant with ISO 10555-1	Compliant with ISO 10555-1	Compliant with ISO 10555-1	• All samples passed two 90° bends without kinking • All samples passed leak testing (up to 8 psi) • Crossing profile was measured and was less than 6.47 mm	• All samples passed two 90° bends without kinking • All samples passed leak testing (up to 8 psi) • Crossing profile was measured and was less than 6.47 mm
Tensile Testing	Compliant with ISO 10555-1	Compliant with ISO 10555-1	Compliant with ISO 10555-1	Compliant with ISO 10555-1	Compliant with ISO 10555-1
Shelf Life	Labeled with a 3-year shelf life.	Unknown	The Endologix Dual Lumen Cathether is labeled with a 3-year shelf life. The device functional, package functional, and packaging sterility has been qualified for this shelf life.	The Endologix IntuiTrak Delivery System is labeled with a 3-year shelf life. The device functional, package functional, and packaging sterility has been qualified for this shelf life.	The Endologix AFX Introducer System is labeled with a 3-year shelf life. The device functional, package functional, and packaging sterility has been qualified for this shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 26 2011

Janet M. Fauls
VP, Regulatory and Clinical Affairs
Endologix, Inc.
11 Studebaker
Irvine, CA 92618

Re: K110090
AFX Introducer System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter, Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 23, 2011
Received: May 25, 2011

Dear Ms. Fauls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

APPENDIX 2

Indications for Use

510(k) Number: K110090

Device Name: Endologix AFX Introducer System

Indications for Use: The AFX Introducer System facilitates the introduction of guidewires, catheters, and other medical devices into the vasculature and minimizes blood loss associated with such introduction.

Prescription Use _____x_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110090